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July 28, 2005

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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

CITIZEN PETITION

The undersigned (the Petitioner) submits this petition in quadruplicate under section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355, and 21 C.F.R. §§ 10.25, 10.30, 314.122 and 314.161 to request the Commissioner of Food and Drugs to determine that the drug Phenergan® (promethazine hydrochloride) 12.5 milligram (mg) and 50 mg tablets (New Drug Application (NDA) No. 07-935) was voluntarily withdrawn from sale for reasons other than safety or effectiveness.

A. ACTION REQUESTED

The Petitioner requests that the Commissioner of Food and Drugs (FDA) make a determination that Wyeth Pharmaceuticals' Phenergan® (promethazine hydrochloride (HCl)) 12.5 mg and 50 mg tablets, NDA No. 07-935 was withdrawn from sale for reasons other than safety and effectiveness.

B. STATEMENT OF GROUNDS

The *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book," contains all drug products approved on the basis of safety and effectiveness. Although FDA approved NDA No. 07-935 for Phenergan® (promethazine HCl) 12.5 mg tablets and 50 mg tablets prior to January 1, 1982, the Orange Book currently lists these drugs in the Discontinued Drug Product List section. The Petitioner believes that Phenergan® is no longer available on the market and has determined that demand exists for the drug on the market in the above strengths and dosage form.

Before FDA can approve an application that references a discontinued drug, FDA must determine whether a discontinued drug was withdrawn for reasons of safety or effectiveness. 21 C.F.R. § 314.161(a). If FDA determines that the drug was not withdrawn for reasons of safety or effectiveness, FDA shall publish a notice in the Federal Register announcing its conclusion. 21 C.F.R. § 314.161(e).

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The Petitioner has no information to suggest that the market withdrawal of Phenergan® 12.5 mg and 50 mg tablets were withdrawn from sale for reasons of safety or effectiveness. On the contrary, since Wyeth Pharmaceuticals continues to market Phenergan® in a 25 mg tablet strength, and FDA lists that strength as a Reference Listed Drug in the Orange Book, we presume that the safety and effectiveness of the promethazine HCl active ingredient is not questioned. Thus, the Petitioner requests that FDA determine the withdrawal from sale was made for reasons other than safety or effectiveness; and therefore an abbreviated new drug application may be filed for promethazine HCl 12.5 mg and 50 mg tablets, pursuant to 21 C.F.R. § 314.122.

C. ENVIRONMENTAL IMPACT

As provided in 21 C.F.R. § 25.31, neither an environmental assessment nor an environmental impact statement is required.

D. ECONOMIC IMPACT

As provided in 21 C.F.R. § 10.30(b), economic impact information will be provided if requested by FDA.

E. CERTIFICATION

The undersigned certifies that to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

Sincerely,
Amide Pharmaceutical, Inc.

Jasmine Shah, M.S., R.Ph.
Director, Regulatory Affairs